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December 18, 2017

Mr. Mitchell Zeller
Director, Center for Tobacco Products
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Re: 82 FR 60206, Docket no. FDA-2017-N-4678, Modified Risk Tobacco Product Applications: Applications for Six Camel Snus Smokeless Tobacco Products Submitted by R.J. Reynolds Tobacco Company; Availability

Dear Mr. Zeller:

Today, December 18, 2017, FDA filed for substantive scientific review six modified risk tobacco product applications (MRTPA) from R.J. Reynolds for six styles of Camel Snus smokeless tobacco products referenced above. We are writing to complain about the public comment process for review of the above-referenced docket.

FDA posted a few of the application materials online today, but left out all the substantive materials. Specifically, Module 3 (Descriptive Information for Camel Snus Smokeless Tobacco Products), Module 4 (Labels, Labeling and Advertising), Module 5 (Environmental Assessments), Module 6 (Summary of All Research Findings), and Module 7 (Scientific Studies and Analyses) -- comprising the core substance and vast majority of the application materials -- were not made available.
https://www.fda.gov/TobaccoProducts/Labeling/MarketingandAdvertising/ucm564399.htm

On its MRTPA webpage today, FDA announced that R.J. Reynolds's MRTPA for Camel Snus is available for public comment, and the comment period closes on June 18, 2018 (in 180 days). https://www.fda.gov/TobaccoProducts/Labeling/TobaccoProductReviewEvaluation/ucm304465.htm#2 However, FDA appended the following note regarding the June 18, 2018 deadline for public comment:

> *There is currently a 180-day public comment period for the R.J. Reynolds Tobacco Company MRTP applications, which we plan to extend, if necessary, to provide additional time for comment as further materials are received and posted.*

While we agree that a 180-day public comment period is reasonable given the anticipated length and complexity of the six MRTP applications, ***the clock should not start ticking until the MRTPA***

is complete and final and all of the application materials (including any and all amendments) have been made available for the public to review.

It is a waste of the public's and researchers' time to look at MRTPAs that are not final, or to review incomplete application materials that can, and likely will, be changed in future amendments. ***Instead, the 180-day public comment period should begin to run only after the MRTPAs are complete, final, unchanging, and all amendments have been posted.***

FDA already has in place a process by which it can Refuse to Accept or Refuse to File incomplete MRTP applications. If FDA needs to work with R.J. Reynolds to ensure that the MRTPA is complete, this should occur *before* the MRTPA is formally filed for public comment. Only after FDA is satisfied that the MRTPA is complete and ready to file should it post the MRTPA for public comment, and only after the MRTPA is complete, final, and posted should the 180-day public comment period begin to run. After the MRTPA is posted and made available for public comment, no further amendments should be permitted.

As it now stands, FDA effectively created a process that precludes careful scientific review and analysis of the MRTPA, and has therefore made a mockery of the public comment process that is mandated by law in sections 911(e) of the Family Smoking Prevention and Tobacco Control Act.

We expressed similar concerns in our December 12, 2017 letter (tracking number 1k1-90bh-d1uh) regarding Philip Morris's MRTPA for its IQOS products, Docket no. FDA-2017-D-3001-3002.

We therefore request that FDA:

1. Remove the R.J. Reynolds MRTPA materials that have been posted to date, and do not post any MRTPA materials, including amendments, unless and until the MRTPAs, including any and all amendments, are complete and final;

2. When the MRTPAs are deemed to be complete and final, FDA should then file the MRTPAs for substantive review and public comment;

3. Once FDA posts the complete and final MRTPAs (including any and all amendments) and makes them available for public comment, no further amendments should be permitted; and

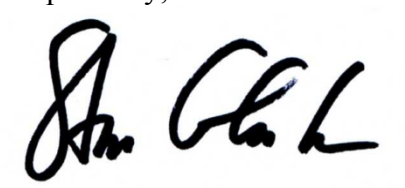
4. Extend the public comment period for the above-referenced docket so that the 180-day public comment period does not start running until the date that the MRTPA is complete and final and made publicly available (i.e., all nine MRTPA modules have been posted, and all amendments have been posted).

Absent such changes, FDA has established a process that is biased against the public interest and in favor of industry.

In particular, we will not ask our colleagues to even look at the R.J. Reynolds MRTP applications until they are complete. At that time, assuming FDA provides 180 days for public comment, we will begin substantive scientific review and analysis of the complete application materials to determine what, if any, comments and recommendations to submit. If FDA does not allow the full 180-day public comment period that is necessary for seriously considering such complex and lengthy materials, we will consider the amount of time that the FDA allows for public comment and

determine if there is enough time to prepare a meaningful public comment. If the time allotted is not adequate, we will simply file a comment so stating.

Respectfully,



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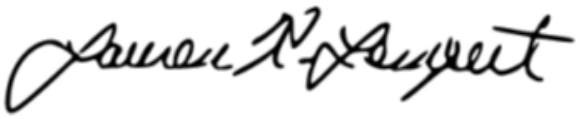

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